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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,998	08/02/2001	Jonathan Swift Stinson	S63.2-9918	5817

490 7590 09/30/2004

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,998

Applicant(s)

STINSON, JONATHAN SWIFT

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 1-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 43-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (5,972,027).

In regard to claims 43-44 and 47, Johnson disclose a stent having pores for receiving drug particles and drug particles including radiochemicals to irradiate and/or prohibit tissue growth or to permit diagnostic imaging of a site (col. 2, lines 15-38), the stent having one region that has a greater porosity volume than other region which inherently accommodates more radiochemical particles than the region that has a lesser porosity volume (figure 5).

In regard to claims 45-46, where the two regions are adjacent another and do not abut one another (figure 5).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson '027. Although, Johnson does not disclose the stent having two regions containing two different radiopaque materials, Johnson suggests different drugs can be loaded into different regions of the stent (col. 4, lines 46-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ different radiochemical materials into different regions of Johnson's stent in order to provide a desired treatment for each of two different adjacent treated regions.

Furthermore, it would have been obvious matter of design choice to modify the Johnson's reference by having a stent with at least two regions having different radiopacities by provide each region with a different radiopaque material, since the applicant has not disclosed that having a stent with at least two regions having different radiopacities by provide each region with a different radiopaque material solves any stated problem or is for any particular purpose and it appears under diagnostic imaging machine that the two regions would perform equally well with either two different radiopaque materials or with the same radiopaque material but different radiopacities.

5. Claims 49-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson '027 in view of Weaver et al. (6,641,776). Johnson disclose a stent having pores for receiving drug particles and drug particles including radiochemicals to irradiate and/or prohibit tissue growth or to permit diagnostic imaging of a site (col. 2, lines 15-38), the stent having one region that has a greater porosity volume than other region which inherently accommodates more radiochemical particles than the region that has a

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lesser porosity volume (figure 5). However, Johnson fails to disclose the type and particle sizes of the particulate radiopaque materials, as claimed.

Weaver et al. disclose employing the type and the particle size of the particulate radiopaque materials, as claimed (see col. 2, lines 45 to col. 5, line 29) into Johnson's stent in order to monitor the stent in a body lumen (col. 5, lines 56-64) and wherein the particulate radiopaque materials mixed with a binder and/or in form of a powder and coated with lubricant agents. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the radiopaque materials as disclosed by Weaver into Johnson, since the particulate radiopaque materials as disclosed by Weaver being designed and made to accommodate on the stent surface as disclosed by Johnson.

In regard to claim 55, although, Johnson and Weaver et al. do not disclose the particulate radiopaque material compounded with a diffusion activating substance boron, it is well known in the art to have the surface of an implanted being coated with lubricating agents, boron or silver. Therefore, it would have been obvious to one skill in the art at the time the invention was made to compound the radiopaque material of Weaver et al. with boron in order to provide lubrication as when in used with the Johnson stent.

Claims 43-47 and 49-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver et al. (6,641,776). Weaver et al. disclose a stent having a plurality of radiopaque regions (wavy rings and connection regions), the radiopaque material is mixed with material of the stent (col. 5, lines 56-64) and a first radiopaque region which

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a wavy ring and a second radiopaque region which is the connection region between the waving ring having different radiopacities since they have different surface area. Although, Weaver et al. do not disclose that the radiopaque material being pressed into the surface and mechanically attached to the surface of the stent, it is well known method for coating the radiopaque material on a medical device. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a known method of pressure treating the radiopaque material on the stent in order to attach the radiopaque material on the stent.

Response to Arguments

6. Applicant's arguments filed 6/7/04 have been fully considered but they are not persuasive. The newly added limitation "which is pressed into the surface and mechanically attached to said surface" places the claims in Product-by-Process condition. MPEP 2113, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. The end product of the claimed invention having the same components and structure as the prior art. Furthermore, Johnson discloses using a high pressure loading to press fit the radiopaque material to the pore meet the broadest reasonable interpretation of "...radiopaque material which is pressed into the surface and mechanically attached to the surface."

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN or NGUYEN can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

September 23, 2004